

FIRST REGULAR SESSION

SENATE BILL NO. 612

94TH GENERAL ASSEMBLY

INTRODUCED BY SENATOR GOODMAN.

Read 1st time February 27, 2007, and ordered printed.

TERRY L. SPIELER, Secretary.

0541S.02I

AN ACT

To repeal sections 191.300, 191.317, and 191.331, RSMo, and to enact in lieu thereof three new sections relating to confidential medical test results.

Be it enacted by the General Assembly of the State of Missouri, as follows:

Section A. Sections 191.300, 191.317, and 191.331, RSMo, are repealed
2 and three new sections enacted in lieu thereof, to be known as sections 191.300,
3 191.317, and 191.331, to read as follows:

191.300. As used in sections 191.300 to 191.380, the following terms
2 mean:

- 3 (1) "Committee", the Missouri genetic disease advisory committee;
- 4 (2) "Cystic fibrosis", a serious lung problem of children; an inherited
5 disorder which produces chronic involvement of the respiratory and digestive
6 systems;
- 7 (3) "Department", the department of health and senior services;
- 8 (4) "Director", the director of the state department of health and senior
9 services;
- 10 (5) "Genetic counseling", the provision and interpretation of medical
11 information based on expanding knowledge of human genetics;
- 12 (6) "Genetic disorders", abnormalities of structure, function, or body
13 metabolism which may be inherited or may result from damage to the fetus;
- 14 (7) "Genetic screening", the search through testing for persons with
15 genetic disorders;
- 16 (8) **"Health care professional", a physician or other health care
17 practitioner licensed, accredited, or certified by the state of Missouri
18 to perform specified health services;**

EXPLANATION—Matter enclosed in bold-faced brackets [thus] in this bill is not enacted and is intended to be omitted in the law.

19 **(9) "Health care services", services for the diagnosis, prevention,**
20 **treatment, cure, or relief of a health condition, illness, injury, or**
21 **disease;**

22 **(10) "Hemophilia", a bleeding tendency resulting from a genetically**
23 **determined deficiency factor in the blood;**

24 **[(9)] (11) "Outreach clinics", medical clinics which provide genetic**
25 **diagnosis and counseling at sites away from the tertiary genetic centers;**

26 **[(10)] (12) "Program", the genetic program authorized by the provisions**
27 **of sections 191.300 to 191.331, 191.340, and 191.365 to 191.380;**

28 **[(11)] (13) "Sickle cell anemia", a blood disease characterized by the**
29 **presence of crescent shaped or sickle shaped erythrocytes in peripheral blood,**
30 **excessive hemolysis, and active hematopoiesis, resulting from a genetic defect;**

31 **[(12)] (14) "Sickle cell trait", the healthy state wherein one carries the**
32 **gene for sickle cell and could possibly pass that gene to his offspring;**

33 **[(13)] (15) "Tertiary genetic centers", permanent genetic divisions that**
34 **provide comprehensive diagnostic treatment and counseling services.**

191.317. **1.** All testing results and personal information obtained from
2 any individual, or from specimens from any individual, shall be held confidential
3 and be considered a confidential medical record, except for such information as
4 the individual, parent or guardian consents to be released; but the individual
5 must first be fully informed of the scope of the information requests to be
6 released, of the risks, benefits and purposes for such release, and of the identity
7 of those to whom the information will be released. Statistical data compiled
8 without reference to the identity of any individual shall not be declared
9 confidential. **Notwithstanding any other law to the contrary, the**
10 **department may release the results of newborn screening tests to a**
11 **child's healthcare professional.**

12 **2. The specimen shall be retained for five years after initial**
13 **submission to the department. After five years, the specimen shall be**
14 **destroyed. Unless otherwise directed under this section, a biological**
15 **specimen may be released for purposes of anonymous scientific study.**
16 **At the time of testing, or up to five years after the specimen was**
17 **initially submitted to the department, the parent or legal guardian of**
18 **the child from whom a biological specimen was obtained may direct the**
19 **department to:**

20 **(1) Return a biological specimen in its entirety and any test**

21 **results after all screening tests have been performed;**

22 **(2) Destroy a biological specimen in a scientifically acceptable**
23 **manner after all screening tests required under section 191.331 or**
24 **regulation have been performed; or**

25 **(3) Store a biological specimen but not release the biological**
26 **specimen for anonymous scientific study.**

27 **3. A biological specimen released for anonymous study under**
28 **this section shall not contain information that may be used to**
29 **determine the identity of the donor.**

191.331. 1. Every infant who is born in this state shall be tested for
2 phenylketonuria and such other metabolic or genetic diseases as are prescribed
3 by the department. The test used by the department shall be dictated by
4 accepted medical practice and such tests shall be of the types approved by the
5 department. All newborn screening tests required by the department shall be
6 performed by the department of health and senior services laboratories. The
7 attending physician, certified nurse midwife, public health facility, ambulatory
8 surgical center or hospital shall assure that appropriate specimens are collected
9 and submitted to the department of health and senior services laboratories.

10 2. All physicians, certified nurse midwives, public health nurses and
11 administrators of ambulatory surgical centers or hospitals shall report to the
12 department all diagnosed cases of phenylketonuria and other metabolic or genetic
13 diseases as designated by the department. The department shall prescribe and
14 furnish all necessary reporting forms.

15 3. The department shall develop and institute educational programs
16 concerning phenylketonuria and other metabolic and genetic diseases and assist
17 parents, physicians, hospitals and public health nurses in the management and
18 basic treatment of these diseases.

19 4. The provisions of this section shall not apply if the parents of such
20 child object to the tests or examinations provided in this section on the grounds
21 that such tests or examinations conflict with their religious tenets and practices.

22 5. As provided in subsection 4 of this section, the parents of any child who
23 fail to have such test or examination administered after notice of the requirement
24 for such test or examination shall be required to document in writing such
25 refusal. All physicians, certified nurse midwives, public health nurses and
26 administrators of ambulatory surgical centers or hospitals shall provide to the
27 parents or guardians a written packet of educational information developed and

28 supplied by the department of health and senior services describing the type of
29 specimen, how it is obtained, the nature of diseases being screened, and the
30 consequences of treatment and nontreatment. The attending physician, certified
31 nurse midwife, public health facility, ambulatory surgical center or hospital shall
32 obtain the written refusal and make such refusal part of the medical record of the
33 infant.

34 6. Notwithstanding the provisions of section 192.015, RSMo, to the
35 contrary, the department may, by rule, annually determine and impose a
36 reasonable fee for each newborn screening test made in any of its
37 laboratories. The department may collect the fee from any entity or individual
38 described in subsection 1 of this section in a form and manner established by the
39 department. Such fee shall be considered as a cost payable to such entity by a
40 health care third party payer, including, but not limited to, a health insurer
41 operating pursuant to chapter 376, RSMo, a domestic health services corporation
42 or health maintenance organization operating pursuant to chapter 354, RSMo,
43 and a governmental or entitlement program operating pursuant to state
44 law. Such fee shall not be considered as part of the internal laboratory costs of
45 the persons and entities described in subsection 1 of this section by such health
46 care third party payers. No individual shall be denied screening because of
47 inability to pay. Such fees shall be deposited in a separate account in the public
48 health services fund created in section 192.900, RSMo, and funds in such account
49 shall be used for the support of the newborn screening program and activities
50 related to the screening, diagnosis, and treatment, including special dietary
51 products, of persons with metabolic and genetic diseases; and follow-up activities
52 that ensure that diagnostic evaluation, treatment and management is available
53 and accessible once an at-risk family is identified through initial screening; and
54 for no other purpose. These programs may include education in these areas and
55 the development of new programs related to these diseases.

56 7. Subject to appropriations provided for formula for the treatment of
57 inherited diseases of amino acids and organic acids, the department shall provide
58 such formula to persons with inherited diseases of amino acids and organic acids
59 subject to the conditions described in this subsection. State assistance pursuant
60 to this subsection shall be available to an applicant only after the applicant has
61 shown that the applicant has exhausted all benefits from third party payers,
62 including, but not limited to, health insurers, domestic health services
63 corporations, health maintenance organizations, Medicare, Medicaid and other

64 government assistance programs. The department shall establish an
65 income-based means test to be used to determine eligibility for the formula made
66 available pursuant to this section.

67 **8. The department shall have authority over the use, retention,**
68 **and disposal of biological specimens and all related information**
69 **collected in connection with newborn screening tests conducted under**
70 **subsection 1 of this section. The use of such specimens and related**
71 **information shall only be made for public health purposes and shall**
72 **comply with all applicable provisions of federal law. The department**
73 **may charge a reasonable fee for the use of such specimens for public**
74 **health research and preparing and supplying specimens for research**
75 **proposals approved by the department.**

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Bill

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